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WARNING LETTER

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

SEP 20 1999

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Victor Jacobs, Chief Executive Officer  
Allou Personal Care Corporation  
d/b/a Stanford Personal Care Manufacturing, Inc.  
50 Emjay Boulevard  
Brentwood, NY 11717

W/L 45-9

Dear Mr. Jacobs:

During an inspection of your manufacturing facility located at 25655 Springbrook Avenue, Bldg. 6, Saugus, CA conducted June 8<sup>th</sup> through June 25<sup>th</sup>, 1999, FDA investigators documented deviations from the Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations (CFR), Part 211). Those deviations cause all drug products manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations from 21 CFR 211 include:

1. Failure to follow written production and process control procedures designed to assure your drug products have the required identity, strength, quality and purity [21 CFR 211.100]. Specifically, you failed to qualify and/or validate the deionized water system after significant changes were made.
2. Failure to write procedures for the cleaning and maintenance of equipment [211.67(b)]. Specifically, you have no written and approved procedure(s) for the cleaning and sanitizing of your upgraded deionized water system. Moreover, the system was observed to be leaking during the inspection.
3. Failure to perform investigations into unexplained discrepancies of a batch or any of its components to meet specifications [211.192]. Specifically, you have not performed follow up investigations when microbial limits exceeded specifications in the deionized water system.

4. Failure to ensure that drug products and in process materials conform to specifications [211.110(b)]. Specifically, your sampling Standard Operating Procedure (SOP) entitled, "[REDACTED] Testing of Water and Water System", calls for [REDACTED] sampling without regard to product manufacturing. There is no assurance that water used in the manufacturing process conforms to specifications on days the water is not sampled.
5. Failure to establish production and process control procedures designed to assure your drug products have the required identity, strength, quality and purity [21 CFR 211.100(a)]. Specifically, you made modifications to the deionized water system without formal change control procedures.
6. Failure to establish appropriate cleaning and maintenance procedures to prevent malfunctions or contamination that would alter the safety, identity, strength and purity of the drug product [211.67(a) and (b)]. There are no or incomplete cleaning validation studies for Ever Ready First Aid Cream, EEZ-Away Arthritis Pain Relief Liquid Analgesic, Naturade Aloe Vera 80 Sunscreen Lotion, SPF-15, Naturade Aloe Vera 80 Sunblock-Sun Defense Lotion, SPF-30, and Naturade Aloe Vera Kids 80 Sunblock Lotion, SPF-30
7. Failure to establish and follow adequate control procedures designed to validate the performance of manufacturing processes that may be responsible for causing variability in the characteristics of the in process material and the drug product [211.110(a)]. Specifically, no process/blend validation studies have been conducted for Ever Ready First Aid Cream. In addition, written procedures for EEZ-Away Arthritis Pain Relief Liquid Analgesic, Naturade Aloe Vera 80 Sunscreen Lotion, Sun Protection Factor (SPF)-15, Naturade Aloe Vera 80 Sunblock-Sun Defense Lotion, SPF-30, and Naturade Aloe Vera Kids 80 Sunblock Lotion, SPF-30 were lacking critical information/tests
8. Failure to write responsibilities and procedures applicable to your quality control unit [211.22(d)].
9. Failure to ensure satisfactory conformance to final specifications through appropriate laboratory determination for both finished drug products and active pharmaceutical ingredients (API) [211.165(a)]. Specifically, you failed to conduct finished product testing on Ever Ready First Aid Cream, EEZ-Away Arthritis Pain Relief Liquid Analgesic, Naturade Aloe Vera 80 Sunscreen Lotion, SPF-15, Naturade Aloe Vera 80 Sunblock-Sun Defense Lotion, SPF-30, and Naturade Aloe Vera Kids 80 Sunblock Lotion, SPF-30 and identity testing of the APIs: lidocaine hydrochloride and phenol.

10. Failure to establish scientifically sound and appropriate specifications to assure that drug products conform to appropriate standards of identity, strength, quality and purity [211.160(b)]. Specifically, you have not performed preservative effectiveness testing for Ever Ready First Aid Cream nor conducted SPF determination studies for Naturade Aloe Vera 80 Sunscreen Lotion, SPF-15, Naturade Aloe Vera 80 Sunblock-Sun Defense Lotion, SPF-30, and Naturade Aloe Vera Kids 80 Sunblock Lotion, SPF-30.
11. Failure to establish and document the accuracy, sensitivity and reproducibility of test methods employed [211.165(e)]. Specifically, there is no Bacteriostasis/Fungistasis testing for Ever Ready First Aid Cream, EEZ-Away Arthritis Pain Relief Liquid Analgesic, Naturade Aloe Vera 80 Sunscreen Lotion, SPF-15, Naturade Aloe Vera 80 Sunblock-Sun Defense Lotion, SPF-30, and Naturade Aloe Vera Kids 80 Sunblock Lotion, SPF-30.
12. Failure to completely follow your testing program Standard Operating Procedures (SOPs) designed to assess the stability characteristics of drug products [211.166(a)]. Specifically, there is no inventory record of stability samples stored in the accelerated and ambient stability chambers and you have not completed stability studies for your Ever Ready First Aid Cream.
13. Failure to prepare batch records with complete information relating to the production and control of each batch [211.188(b)]. Specifically, there are no statements of theoretical yield, no sampling and testing procedures, no specified mixing times and no label specimen.
14. Failure to ensure that all people engaged in the manufacture, processing, packing or holding of a drug product have the education, training and/or experience to perform their assigned functions [211.25(a)]. Specifically, your training records do not indicate the topic(s) covered during training and they do not specify the date(s) of the training.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your Saugus, CA facility. At the conclusion of the inspection, a FDA Form 483, Inspectional Observations, was issued to Mr. John A. Mizialo, Executive Vice President (copy enclosed). It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, New Drug Applications, Abbreviated New Drug Applications or export approval requests may not be approved until the above violations are corrected.

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You should take prompt action to correct these deviations. **Failure** to promptly correct these deviations may result in regulatory action without **further notice**. Possible actions include seizure and/or injunction.

Many inspectional observations listed here and on the FDA-483 (see enclosure) are similar to those for which your firm has been cited as a **result** of previous cGMP inspections. We acknowledge the commitment made **during** the inspection to not manufacture any OTC drug products until after the deionized **water** system is validated. However, you should be aware that we consider several of **the** FDA-483 observations (lack of a written QC system, lack of stability data, lack of various process validation(s) and some method validations) to be highly significant. In **addition**, you have had two recalls over the past eighteen months related to microbiological contamination of products manufactured at your facility.

During the inspection, we sampled your hair gel product "EURO TEEZER NATURA VOLUMIZING GEL". These samples were tested at our FDA laboratory; lots "9D8853" and "9D8861" were confirmed to be contaminated with *Pseudomonas fluorscens*. These findings reinforce the absolute need to assure your water system is not introducing contaminants, and continues to operate within specifications for future production. Therefore, we request that you contact this office to arrange a meeting with us to discuss the serious nature of these violations.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen days, state the reason for the delay and the time within which corrections will be completed.

Your written response should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612  
Phone: 949-798-7755

Sincerely,

  
Acting District Director

Enclosure: FDA Form 483, Inspectional Observations